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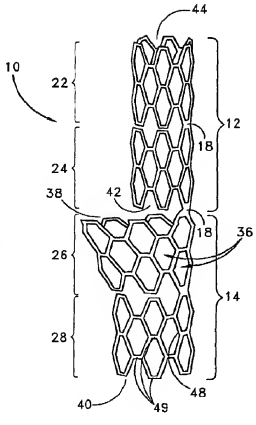

(57) Abstract: A device is configured for treating pathological narrowing of fluid-carrying conduits of the human body (such as blood vessels) in an area of a bifurcation (30). In particular, a stent delivery system (100) configured to carry one or more of a pair of dissimilar stents (12, 14). At least one of the stents (12, 14) is particularly suited for treating a widened portion of a blood vessel (46) immediately proximal to a bifurcation (30). The stent delivery system (100) can also include a handpiece (140) adapted to selectively deliver the stents.

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ENDOPROSTHESIS DEPLOYMENT SYSTEM FOR TREATING VASCULAR BIFURCATIONS

Background

Scope of the Invention

The present invention relates to an apparatus permitting the treatment of bodily conduits, typically blood vessels, in an area of a bifurcation, e.g. in an area where a principal conduit separates into two secondary conduits. It also relates to equipment for positioning this apparatus.

Description of the Related Art

It is known to treat narrowing of a rectilinear blood vessel by means of a radially expandable tubular device, commonly referred to as a stent. This stent is introduced in the unexpanded state into the internal lumen of the vessel, in particular by the percutaneous route, as far as the area of narrowing. Once in place, the stent is expanded in such a way as to support the vessel wall and thus re-establish the appropriate cross section of the vessel.

Stent devices can be made of a non-elastic material, in which case the stent is expanded by an inflatable balloon on which it is engaged. Alternatively, the stent can be self-expanding, e.g. made of an elastic material. A self-expanding stent typically expands spontaneously when withdrawn from a sheath which holds it in a contracted state.

For example, United States Patent Nos. 4,733,065 and 4,806,062 illustrate existing stent devices and corresponding positioning techniques.

A conventional stent is not entirely suitable for the treatment of a narrowing situated in the area of a bifurcation, since its engagement both in the principal conduit and in one of the secondary conduits can cause immediate or delayed occlusion of the other secondary conduit.

It is known to reinforce a vascular bifurcation by means of a stent comprising first and second elements, each formed by helical winding of a metal filament. The first of the two elements has a first part having a diameter corresponding to the diameter of the principal vessel, and a second part having a diameter corresponding to the diameter of a first one of the secondary vessels. The first element is intended to be engaged in the principal vessel and the second element is intended to be engaged in the first secondary vessel. The second element has a diameter corresponding to the diameter of the second

secondary vessel. After the first element has been put into place, the second element is then coupled to the first element by engaging one or more of its turns in the turns of the first element.

This equipment permits reinforcement of the bifurcation but appears unsuitable for treating a vascular narrowing or an occlusive lesion, in view of its structure and of the low possibility of radial expansion of its two constituent elements.

Moreover, the shape of the first element does not correspond to the shape of a bifurcation, which has a widened transitional zone between the end of the principal vessel and the ends of the secondary vessels. Thus, this equipment does not make it possible to fully support this wall or to treat a dissection in the area of this wall. Additionally, the separate positioning of these two elements is quite difficult.

Summary of the Invention

There is provided in accordance with one aspect of the present invention, a method of treating a vascular bifurcation of a main vessel into a first and a second branch vessels. The method comprises the steps of providing a delivery catheter having a stent thereon, the stent having a proximal end and a distal end and being self expandable to a configuration in which the proximal end has a smaller diameter than the distal end. The catheter is positioned such that the stent is at a treatment site within the main vessel, with the distal end adjacent the bifurcation. The stent is deployed in the main vessel such that the distal end communicates with both the first and the second branch vessels.

In one implementation of the invention, the method additionally comprises the step of dilating the treatment site prior to the positioning step. The deploying step may comprise removing a restraint from the stent and permitting the stent to self expand. The method may additionally comprise the step of deploying a second stent in one of the first and second branch vessels.

In one implementation of the invention, the distal end of the stent expands to a diameter that is at least about 105% of the diameter of the proximal end of the stent. In certain applications, the distal end of the stent expands to a diameter that is at least about 110% of the diameter of the proximal end of the stent.

In accordance with another aspect of the present invention, there is provided a deployment system for treating a bifurcation of a main vessel into a first and second branch vessels. The deployment system comprises an elongate flexible body, having a proximal

end and a distal end. A tapered stent is carried by the distal end of the body. A releasable restraint for restraining the stent is also carried by the body. The distal end of the stent is larger in diameter than the proximal end of the stent in an unconstrained expanded configuration.

The deployment system may additionally comprise a guidewire lumen extending axially through at least a portion of the flexible body. The guidewire lumen has a proximal access port and a distal access port. In one implementation, the proximal access port is positioned along the flexible body, spaced distally apart from the proximal end. In another implementation, the proximal access port is positioned at the proximal end of the body.

The releasable restraint may comprise an axially moveable control element extending along the length of the flexible body. The releasable restraint may also comprise a tubular sheath, for restraining the stent. The tubular sheath may be attached to an axially moveable pull wire.

In accordance with a further aspect of the present invention, there is provided a method of treating a vascular bifurcation of a main vessel into first and second branch vessels. The method comprises the steps of deploying a substantially cylindrical stent in a first branch vessel which is distal to the bifurcation, and deploying a tapered stent in the main vessel, proximal to the bifurcation. The tapered stent tapers in a distal direction from a smaller proximal diameter to a larger distal diameter which faces the bifurcation.

In accordance with another aspect of the present invention, there is provided a stent deployment catheter. The catheter comprises an elongate flexible tubular body, having a proximal end and a distal end. A noncylindrical, self expandable stent is carried by the distal end. A hand piece is provided on the proximal end. A control is provided on the hand piece, for controllably removing a restraint from the noncylindrical self expandable stent. In one application, the control has a first position for indicating a partial deployment of the stent, and a second position indicating complete deployment of the stent.

All of these embodiments are intended to be within the scope of the present invention herein disclosed. These and other embodiments of the present invention will become readily apparent to those skilled in the art from the following detailed description of the preferred embodiments having reference to the attached figures, the invention not being limited to any particular embodiment(s) disclosed.

Brief Description of the Drawings

Having thus summarized the general nature of the invention, certain preferred embodiments and modifications thereof will become apparent to those skilled in the art from the detailed description herein having reference to the attached figures, of which:

Figure 1 is a side view of a first embodiment of a stent system shown in an expanded state;

Figure 2 is a perspective, partial cutaway view of the stent system of Figure 1 shown in a state of radial contraction, as disposed on a delivery catheter;

Figure 3 is a longitudinal sectional view of a bifurcation treatable by the stent system of Figure 1;

Figure 4 is a section view of the bifurcation of Figure 3 showing a delivery catheter positioned therein;

Figure 5 is a section view of the bifurcation of Figure 3 showing an embodiment of a stent system shown in a partially contracted state on a portion of a delivery catheter;

Figure 6 is a section view of the bifurcation of Figure 3 showing an embodiment of a stent system shown in an expanded and fully deployed state;

Figure 7 is a section view of a bifurcation presenting an aneurysm and an embodiment of a stent system shown deployed therein,

Figure 8 is a side view of a stent system according to a second embodiment shown in an expanded state;

Figure 9 is a plan view of a delivery catheter usable to deploy a stent system having certain features and advantages;

Figure 9A is an alternative embodiment of a proximal handpiece of the delivery catheter of Figure 9;

Figure 9B is an alternative embodiment of the delivery catheter of Figure 9;

Figure 9C is a section view of a portion of the delivery catheter of Figure 9 taken through line 9C-9C and specifically showing an alternative pull wire lumen;

Figure 9D is a section view of a portion of the delivery catheter of Figure 9 taken through line 9D-9D and specifically showing a retaining band;

Figure 9E is a detail view of a retraction band retention assembly of the delivery catheter of Figure 9;

Figure 10 is a partial cutaway view of a distal portion of the catheter of Figure 9 including a stent system disposed thereon;

Figure 10A is an alternative embodiment of a distal end assembly of the delivery catheter of Figure 9B;

Figure 10B is a detail view of a distal portion of the outer sheath shown in Figure 10;

Figure 10C is a section view taken along the line 10C-10C of Figure 10;

Figure 11A is a plan view of a transitional portion of the catheter of Figure 9;

Figure 11B is a cross sectional view of the transitional portion taken along the line 11B-11B of Figure 11A;

Figure 11C is a transverse sectional view of the transitional portion taken along the line 11C-11C of Figure 11A;

Figure 11D is a cross sectional view of the proximal shaft taken along the line 11D-11D of Figure 11A;

Figure 12 is a side section view of a distal portion of an embodiment of a delivery catheter having certain features and advantages;

Figure 13 is a section view of a bifurcation showing an embodiment of a delivery catheter positioned therein;

Figure 14 is a section view of a bifurcation showing a first stent in a partially deployed state;

Figure 15 is a section view of a bifurcation showing a first stent in a fully deployed state;

Figure 16 is a section view of a bifurcation showing a second stent in a partially deployed state;

Figure 17 is a section view of a bifurcation showing a second stent in a fully deployed state;

Figure 18 is a section view of a bifurcation as in Figure 17, with a second branch stent deployed in the second branch;

Figure 19 is a schematic elevation view of a single-stent delivery system for delivering a cylindrical stent;

Figure 20 is a schematic elevation view of the single-stent delivery system of Figure 19 showing the sheath in a proximal detail view;

Figure 21 is a schematic elevation view of a single-stent delivery system for delivering a conical stent; and

Figure 22 is a schematic elevation view of the single-stent delivery system of Figure 21 showing the sheath in a proximal detail view.

Detailed Description of the Preferred Embodiment

As described above, the attached Figures illustrate a stent system and corresponding delivery system for use in treating vessels (e.g. conduits) within the human body at areas of bifurcations. Figure 3 shows a bifurcation **30** in which a main conduit or vessel **32** separates into two secondary branch conduits or vessels **34**. The stent system generally includes a pair of dissimilar stents specifically designed for use in an area of a bifurcation **30**. Such dissimilar stents are then disposed on an elongate catheter for insertion into the human body. The dissimilar stents may be self-expanding or manually expandable such as by a balloon about which the stents may be disposed as will be described in further detail below.

Figure 1 shows one embodiment of an expandable stent system **10** permitting the treatment of bodily conduits in the area of a bifurcation such as that shown. The stent system **10**, shown in an expanded state in Figure **1**, generally comprises first **12** and second **14** stent portions which may each be divided into two segments, thus creating four successive segments **22, 24, 26, 28**, of meshwork structure. The first stent **12** is generally adapted to be disposed in a branch conduit or vessel **34** of a bifurcation, while the second stent **14** is generally adapted to be disposed in a main vessel **32**. If desired, the segments may be connected to one another via one or more bridges of material **18**. The stents **12, 14** are generally movable between a contracted position and an expanded position. As will be clear to those skilled in the art, the stents may be self-expanding or balloon-expandable.

According to the illustrated embodiment, the stents **12, 14** generally comprise an expandable mesh structure which includes a plurality of mesh cells **36**. The mesh cells **36** of these segments are in one embodiment elongated in the longitudinal direction of the stents **12, 14** and have in each case a substantially hexagonal shape in the embodiment shown. Those skilled in the art will recognize that the mesh used to form the stent segments **22, 24, 26,** and **28** may comprise a variety of other shapes known to be suitable

for use in stents. For example a suitable stent may comprise mesh with repeating quadrilateral shapes, octagonal shapes, a series of curvatures, or any variety of shapes such that the stent is expandable to substantially hold a vessel or conduit at an enlarged inner diameter.

The first stent **12** may be divided into two segments **22** and **24** which may be identical to each other and typically have a tubular shape with a diameter which is substantially greater than the diameter of one of the secondary branch conduits **34**. Those skilled in the art will recognize that the first stent may comprise a variety of shapes such that it functions as described herein. The first stent **12** may be expandable to a substantially cylindrical shape having a constant diameter along its length. The first stent **12** may comprise a range of lengths depending on the specific desired location of placement. For example, the length of the first stent **12** will typically be between about 1 and about 4 centimeters as desired.

The second stent **14** is preferably adapted to be deployed in close proximity to the first stent **12**, and may also be divided into upper **26** and lower **28** segments. The lower segment **28** of the second stent **14** typically has a tubular cross-sectional shape and has an expanded diameter which is substantially greater than the diameter of the principal conduit **32** (Figure 3). The upper segment **26** of the second stent **14** preferably comprises a larger diameter at its distal (upper) end **38** than at its proximal (lower) end **40**. In one embodiment the upper segment of the second stent portion comprises a substantially conical shape. In an alternative embodiment, the second stent **14** may be tapered radially outward along its entire length in the distal direction. In either embodiment however, the expanded diameter of the distal end **38** of the second stent **14** is preferably substantially larger than the expanded diameter of the proximal end **42** of the first stent **12**. For example, the distal end **38** of the second stent **14** may expand to a diameter that is at least about 105%, and preferably at least about 110%, and in some embodiments as much as 120% or more, of the diameter of the proximal end **42** of the first stent **12**. The second stent **14** may comprise a range of lengths depending on the specific desired location of placement. For example, the second stent **14** will typically be between 1 and 4 centimeters as desired.

In its expanded state, as shown in Figure **1**, the upper segment **26** of the second stent **14** typically has mesh cells **36** whose width increases progressively, compared to that of the meshes of the lower segment **28**, on the one hand in the longitudinal sense of the dual stent

device **10**, in the direction of the distal end **38** of the second stent **14**, and, on the other hand, in the transverse sense of the second stent **14**, in the direction of a generatrix diametrically opposite that located in the continuation of the bridge **18**. Alternatively stated, the upper segment **26** of the second stent **14** preferably comprises a mesh with multiple cellular shapes **36** which may have larger dimensions at a distal end **38** of the stent **14** than those at the proximal end **40** such that the second stent 14 expands to a substantially funnel shape.

In the embodiment shown, this increase in the width of the mesh cells **36** results from an increase in the length of the edges **48** of the mesh cells **36** disposed longitudinally, as well as an increase in the angle formed between two facing edges **48**.

This segment **26** thus may have a truncated shape with an axis which is oblique in relation to the longitudinal axis of the first stent **12** when expanded. This shape, for example, corresponds to the shape of the bifurcation shown in the area of the widened transitional zone **46** (Figure 3) which separates the end of the principal conduit **32** from the ends of the secondary conduits **34**. In a preferred embodiment, the second stent **14** is placed in close proximity to the first stent **12**. For example, the distal end **38** of the second stent **14** is preferably placed within a distance of about 4 mm of the distal end **42** of the first stent **12**, more preferably this distance is less than about 2 mm, and most preferably the stents are placed within 1 mm of one another.

In the embodiment shown in Figure **1**, the distance between first and second stents **12**, **14** is held substantially fixed by the provision of a bridge **18** between them. Bridges **18** may be provided to join the first and second stents **12**, **14** to one another and/or to join the upper and lower segments **22**, **24** and **26**, **28** of each stent **12** and **14** together. If present, the bridges **18** may connect the adjacent ends of the segments **22**, **24** and **26**, **28** and typically have a small width, so that they can undergo a certain flexion, making it possible to orient these segments in relation to one another, in particular the lower segment **24** of the first stent **12** in relation to the upper segment **26** of the second stent **14**.

In addition, in other embodiments, the bridges **18** could be integral with one of the connected segments and separately connected, such as by welding, to the other connected segment. For example, the bridge **18** which connects the first and second stents **12**, **14** could be integral with the upper segment **26** of the second stent **14** and connected to lower segment **24** of the first segment **26**. Alternatively, the bridge **18** could be integral with the

lower segment **24** of the first stent **12** and connected to the upper segment **26** of the second stent **14**.

In yet other embodiments, bridges **18** could be separate pieces of materials which are separately connected to segments **22, 24, 26, 28** such as by welding, adhesion, or other bonding method. In all of these embodiments, the first stent **12** can be made from different pieces of material than the second stent **14**. A tube from which the first stent **12** may be made (e.g. by laser cutting techniques) may comprise a smaller diameter than a tube from which the second stent **14** may be made. The respective tubes may or may not be made of the same material. Alternatively, the first and second stent may be formed from a single piece of material.

When the segments **26** and **28** of the second stent **14** are made from tubes of a smaller diameter than the segments **22** and **24** of the first stent **12**, the radial force of the first stent segments **22** and **24** is larger than the radial force of the second stent segments **26** and **28**, especially at larger cross sections.

Accordingly, bridges **18** can be made from one of these tubes, and thus be integral with segments **22** and **24** or segments **26** and **28**. Alternatively, the bridges **18** can be separate pieces of material.

In further embodiments, bridges **18** are omitted such that the individual segments are spaced as desired during installation and use. These individual segments are still delivered and implanted in the same core and sheath assembly.

The bridges **18** between two consecutive segments could be greater or smaller in number than six, and they could have a shape other than an omega shape, permitting their multidirectional elasticity, and in particular a V shape or W shape.

For example, Figure 8 shows an alternative embodiment of the stent system **10** with first **12** and second **14** stents shown in their unconstrained, expanded states. According to this embodiment, each stent **12, 14** may be divided into two segments **22, 24** and **26, 28** and may include one or more flexible bridges **18** connecting the first **12** and second stents **14** to one another. In this embodiment, the two consecutive segments **22, 24** and **26, 28** of the first and second stents **12** and **14**, are connected by a plurality (e.g. six) omega-shaped bridges **50**. The curved central part **52** of these bridges **50** may have a multidirectional elasticity permitting the appropriate longitudinal orientation of the various segments in relation to one another. The advantage of these bridges **50** is that they provide the stent

with longitudinal continuity, which facilitates the passage of the stent system into a highly curved zone and which eliminates the need to reduce this curvature, (which may be dangerous in the cases of arteriosclerosis).

Thus, the stent system **10** of Figure 8 can comprise several segments **22**, **24**, **26**, **28** placed one after the other, in order to ensure supplementary support and, if need be, to increase the hold of the stents in the bifurcation **30**. The upper segment **26** of the second stent **14** could have an axis coincident with the longitudinal axis of the first stent, and not oblique in relation to this axis, if such is rendered necessary by the anatomy of the bifurcation which is to be treated.

Alternatively, the lower segment **24** of the first stent **12** could itself have, in the expanded state, a widened shape similar to that of the second stent and corresponding to the shape of the widened connecting zone (increasing diameter in the proximal direction) by which, in certain bifurcations, the secondary conduits **34** are connected to the widened transition zone **46**. Thus, the lower segment **24** of the first stent **12**, or the entire first stent **12** may have a first diameter at its distal end, and a second, larger diameter at its proximal end with a linear or progressive curve (flared) taper in between. According to this embodiment, this segment **24** would thus have a shape corresponding to the shape of this widened connecting zone, and would ensure perfect support thereof.

One method of making a self-expanding stent is by appropriate cutting of a sheet of nickel/titanium alloy (for example, an alloy known by the name NITINOL may appropriately be used) into a basic shape, then rolling the resulting blank into a tubular form. The blank may be held in a cylindrical or frustroconical form by welding the opposing edges of this blank which come into proximity with each other. The stent(s) may also be formed by laser cutting from metal tube stock as is known in the art. Alternatively, a stent may be formed by selectively bending and forming a suitable cylindrical or noncylindrical tubular shape from a single or multiple wires, or thin strip of a suitable elastic material. Those skilled in the art will understand that many methods and materials are available for forming stents, only some of which are described herein.

Some Nickel Titanium alloys are malleable at a temperature of the order of 10 °C but can recover a neutral shape at a temperature substantially corresponding to that of the human body. Figure 2 shows the stent system **10** disposed on a delivery catheter in a state of radial contraction. In one embodiment, a self-expanding stent may be contracted by

cooling its constituent material of nickel-titanium or other shape-memory alloy to a temperature below its transformation temperature. The stent may later be expanded by exposing it to a temperature above the transformation temperature. In the present use, a shape-memory alloy with a transformation temperature at or below normal body temperature may be used. Those skilled in the art will recognize that a self-expanding stent made of a substantially elastic material may also be mechanically contracted from its expanded shape by applying a radial compressive force. The stent may then be allowed to expand under the influence of the material's own elasticity. Nickel titanium and other alloys such as such as Silver-Cadmium (Ag-Cd), Gold-Cadmium (Au-Cd) and Iron-Platinum (Fe_3-Pt), to name but a few offer desirable superelastic qualities within a specific temperature range.

In one embodiment, the contraction of a stent may cause the mesh cell edges **48** to pivot in relation to the transverse edges **49** of the mesh cells **36** in such a way that the mesh cells **36** have, in this state of contraction, a substantially rectangular shape. Those skilled in the art will recognize that other materials and methods of manufacturing may be employed to create a suitable self-expanding stent.

Alternatively, the stents used may be manually expandable by use of an inflatable dilatation balloon with or without perfusion as will be discussed further below. Many methods of making balloon-expandable stents are known to those skilled in the art. Balloon expandable stents may be made of a variety of bio-compatible materials having desirable mechanical properties such as stainless steel and titanium alloys. Balloon-expandable stents preferably have sufficient radial stiffness in their expanded state that they will hold the vessel wall at the desired diameter. In the case of a balloon-expandable second stent **14**, the balloon on which the second stent **14** is disposed may be specifically adapted to conform to the desired shape of the second stent **14**. Specifically, such a balloon will preferably have a larger diameter at a distal end than at a proximal end.

The present discussion thus provides a pair of dissimilar stents permitting the treatment of a pathological condition in the area of a bifurcation **30**. This system has the many advantages indicated above, in particular those of ensuring a perfect support of the vessel wall and of being relatively simple to position.

For the sake of simplification, the segment which has, in the unconstrained expanded state, a cross section substantially greater than the cross section of one of the

secondary conduits will be referred to hereinafter as the "secondary segment", while the segment which has, in the expanded state, a truncated shape will be referred to hereinafter as the "truncated segment."

The secondary segment is intended to be introduced into the secondary conduit in the contracted state and when expanded will preferably bear against the wall of the conduit. This expansion not only makes it possible to treat a narrowing or a dissection situated in the area of the conduit, but also to ensure perfect immobilization of the apparatus in the conduit.

In this position, the truncated segment bears against the wall of the conduit delimiting the widened transitional zone of the bifurcation, which it is able to support fully. A narrowing or a dissection occurring at this site can thus be treated by means of this apparatus, with uniform support of the vascular wall, and thus without risk of this wall being damaged.

The two segments may be adapted to orient themselves suitably in relation to each other upon their expansion.

Advantageously, at least the truncated segment may be covered by a membrane (for example, Dacron® or ePTFE) which gives it impermeability in a radial direction. This membrane makes it possible to trap between it and the wall of the conduit, the particles which may originate from the lesion being treated, such as arteriosclerotic particles or cellular agglomerates, thus avoiding the migration of these particles in the body. Thus, the apparatus can additionally permit treatment of an aneurysm by guiding the liquid through the bifurcation and thereby preventing stressing of the wall forming the aneurysm.

The segments can be made from tubes of material of a different diameter, as discussed above, with the tube for the truncated segment having a larger diameter than the tube for the secondary segment. The tubes may be made from the same material. The use of tubes of different diameters can result in the truncated segment having a larger radial force, especially at larger diameters.

The apparatus can comprise several secondary segments, placed one after the other, to ensure supplementary support of the wall of the secondary conduit and, if need be, to increase the anchoring force of the stent in the bifurcation. To this same end, the apparatus can comprise, on that side of the truncated segment directed toward the principal conduit, at

least one radially expandable segment having, in the expanded state, a cross section which is substantially greater than the cross section of the principal conduit.

These various supplementary segments may or may not be connected to each other and to the two aforementioned segments by means of flexible links, such as those indicated above.

The flexible links can be integral with one of the segments and separately connected to the other segment, or the flexible links can be separate pieces of material separately connected to both segments, such as by welding.

Preferably, the flexible link between two consecutive segments is made up of one or more bridges of material connecting the two adjacent ends of these two segments. Said bridge or bridges are advantageously made of the same material as that forming the segments.

Each segment may have a meshwork structure, the meshes being elongated in the longitudinal direction of the stent, and each one having a substantially hexagonal shape; the meshes of the truncated segment may have a width which increases progressively in the longitudinal sense of the stent, in the direction of the end of this segment having the greatest cross section in the expanded state.

This increase in the width of the meshes is the result of an increase in the length of the edges of the meshes disposed longitudinally and/or an increase in the angle formed between two facing edges of the same mesh.

In addition, the truncated segment can have an axis not coincident with the longitudinal axis of the secondary segment, but oblique in relation to this axis, in order to be adapted optimally to the anatomy of the bifurcation which is to be treated. In this case, the widths of the meshes of the truncated segment also increase progressively, in the transverse sense of the stent, in the direction of a generatrix diametrically opposite that located in the continuation of the bridge connecting this segment to the adjacent segment.

The apparatus can be made of a metal with shape memory, which becomes malleable, without elasticity, at a temperature markedly lower than that of the human body, in order to permit retraction of the apparatus upon itself, and to allow it to recover its neutral shape at a temperature substantially corresponding to that of the human body. This metal may be a nickel/titanium alloy known by the name NITINOL.

The deployment catheter for positioning the stent or stents comprises means for positioning the stents and means for permitting the expansion of the stents when the latter are in place. These means can comprise a catheter having a removable sheath in which the stent is placed in the contracted state, when this stent is made of an elastic material, or a support core comprising an inflatable balloon on which the stent is placed, when this stent is made of a nonelastic material.

In either case, this equipment comprises, according to the invention, means with which it is possible to identify and access, through the body of the patient, the longitudinal location of the truncated segment, so that the latter can be correctly positioned in the area of the widened zone of the bifurcation.

In the case where the expansion of this same segment is not uniform in relation to the axis of the stent, the equipment additionally comprises means with which it is possible to identify, through the body of the patient, the angular orientation of the stent in relation to the bifurcation to be treated, so that the part of this segment having the greatest expansion can be placed in a suitable manner in relation to the bifurcation.

Referring to FIG. 9, the stent system is generally deployed using an elongate flexible stent deployment catheter **100**. Although primarily described in the context of a multiple stent placement catheter without additional functional capabilities, the stent deployment catheter described herein can readily be modified to incorporate additional features such as an angioplasty balloon or balloons, with or without perfusion conduits, radiation or drug delivery capabilities, or stent sizing features, or any combination of these features, as will be readily apparent to one of skill in the art in view of the disclosure herein.

The elongate delivery catheter **100** generally includes a proximal end assembly **102**, a proximal shaft section **110** including a tubular body **111**, a distal shaft section **120** including a distal tubular body **113**, and a distal end assembly **107**. The proximal end **102** may include a handpiece **140**, having one or more hemostatic valves and/or access ports **106**, such as for the infusion of drugs, contrast media or inflation media in a balloon expandable stent embodiment, as will be understood by those of skill in the art. In addition, a proximal guidewire port **172** may be provided on the handpiece **140** in an over the wire embodiment (see Figure **9A**). The handpiece **140** disposed at the proximal end of the catheter **100** may also be adapted to control deployment of the stents disposed on the catheter distal end **104** as will be discussed.

The length of the catheter depends upon the desired application. For example, lengths in the area of about 120 cm to about 140 cm are typical for use in coronary applications reached from a femoral artery access. Intracranial or lower carotid artery applications may call for a different catheter shaft length depending upon the vascular access site, as will be apparent to those of skill in the art.

The catheter **100** preferably has as small an outside diameter as possible to minimize the overall outside diameter (e.g. crossing profile) of the delivery catheter, while at the same time providing sufficient column strength to permit distal transluminal advancement of the tapered tip **122**. The catheter **100** also preferably has sufficient column strength to allow an outer, axially moveable sheath **114** to be proximally retracted relative to the central core **112** in order to expose the stents **118**. The delivery catheter **100** may be provided in either "over-the-wire" or "rapid exchange" types as will be discussed further below, and as will generally be understood by those skilled in the art.

In a catheter intended for peripheral vascular applications, the outer sheath **114** will typically have an outside diameter within the range of from about 0.065 inches to about 0.092 inches. In coronary vascular applications, the outer sheath **114** may have an outside diameter with the range of from about 0.039 inches to about 0.065. Diameters outside of the preferred ranges may also be used, provided that the functional consequences of the diameter are acceptable for the intended purpose of the catheter. For example, the lower limit of the diameter for any portion of catheter **100** in a given application will be a function of the number of guidewire, pullwire or other functional lumen contained in the catheter, together with the acceptable minimum flow rate of dilatation fluid, contrast media or drugs to be delivered through the catheter and minimum contracted stent diameter.

The ability of the catheter **100** to transmit torque may also be desirable, such as to avoid kinking upon rotation, to assist in steering, and in embodiments having an asymmetrical distal end on the proximal stent 14. The catheter **100** may be provided with any of a variety of torque and/or column strength enhancing structures, for example, axially extending stiffening wires, spiral wrapped support layers, or braided or woven reinforcement filaments which may be built into or layered on the catheter **100**. See, for example, U.S. Pat. No. 5,891,114 to Chien, et al., the disclosure of which is incorporated in its entirety herein by reference.

Referring to FIG. **11D**, there is illustrated a cross-sectional view through the proximal section **106** of the catheter shaft **100** of **FIG. 9**. The embodiment shown in Figure **11D** represents a rapid exchange embodiment, and may comprise a single or multiple lumen extrusion or a hypotube including a pull wire lumen **220**. In an over-the-wire embodiment, the proximal section **106** additionally comprises a proximal extension of a guidewire lumen **132** and a pull wire lumen **220**. The proximal tube **111** may also comprise an inflation lumen in a balloon catheter embodiment as will be understood by those skilled in the art.

At the distal end **107**, the catheter is adapted to retain and deploy one or more stents within a conduit of a human body. With reference to Figures **10A** and **12**, the distal end assembly **107** of the delivery catheter **100** generally comprises an inner core **112**, an axially moveable outer sheath **114**, and optionally one or more inflatable balloons **116** (Fig. **12**). The inner core **112** is preferably a thin-walled tube at least partially designed to track over a guidewire, such as a standard 0.014 inch guidewire. The outer sheath **114** preferably extends along at least a distal portion **120** of the central core **112** on which the stents **118** are preferably disposed.

The outer sheath **114** may extend over a substantial length of the catheter **100**, or may comprise a relatively short length, distal to the proximal guidewire access port **172** as will be discussed. In general, the outer sheath **114** is between about 5 and about 25 cm long.

Referring to Figure **10**, the illustrated outer sheath **114** comprises a proximal section **115**, a distal section **117** and a transition **119**. The proximal section **115** has an inside diameter which is slightly greater than the outside diameter of the tubular body **113**. This enables the proximal section **115** to be slideably carried by the tubular body **113**. Although the outer sheath **114** may be constructed having a uniform outside diameter throughout its length, the illustrated outer sheath **114** steps up in diameter at a transition **119**. The inside diameter of the distal section **117** of outer sheath **114** is dimensioned to slideably capture the one or more stents as described elsewhere herein. In a stepped diameter embodiment such as that illustrated in Figure **10**, the axial length of the distal section **117** from the transition **119** to the distal end is preferably sufficient to cover the stent or stents carried by the catheter **100**. Thus, the distal section **117** in a two stent embodiment is generally at least about 3 cm and often within the range of from about 5 cm to about 10 cm in length.

The axial length of the proximal section **115** can be varied considerably, depending upon the desired performance characteristics. For example, proximal section **115** may be as short as one or two centimeters, or up to as long as the entire length of the catheter. In the illustrated embodiment, the proximal section **115** is generally within the range of from about 5 cm to about 15 cm long.

The outer sheath **114** and inner core **112** may be produced in accordance with any of a variety of known techniques for manufacturing rapid exchange or over the wire catheter bodies, such as by extrusion of appropriate biocompatible polymeric materials. Known materials for this application include high and medium density polyethylenes, polytetrafluoroethylene, nylons, PEBAX, PEEK, and a variety of others such as those disclosed in U.S. Pat. No. 5,499,973 to Saab, the disclosure of which is incorporated in its entirety herein by reference. Alternatively, at least a proximal portion or all of the length of central core **112** and/or outer sheath **114** may comprise a metal or polymeric spring coil, solid walled hypodermic needle tubing, or braided reinforced wall, as is understood in the catheter and guidewire arts.

The distal portion **117** of outer sheath **114** is positioned concentrically over the stents **118** in order to hold them in their contracted state. As such, the distal portion **117** of the outer sheath **114** is one form of a releasable restraint. The releasable restraint preferably comprises sufficient radial strength that it can resist deformation under the radial outward bias of a self-expanding stent. The distal portion **117** of the outer sheath **114** may comprise a variety of structures, including a spring coil, solid walled hypodermic needle tubing, banded, or braided reinforced wall to add radial strength as well as column strength to that portion of the outer sheath **114**. Alternatively, the releasable restraint may comprise other elements such as water soluble adhesives or other materials such that once the stents are exposed to the fluid environment and/or the temperature of the blood stream, the restraint material will dissolve, thus releasing the self-expandable stents. A wide variety of biomaterials which are absorbable in an aqueous environment over different time intervals are known including a variety of compounds in the polyglycolic acid family, as will be understood by those of skill in the art. In yet another embodiment, a releasable restraint may comprise a plurality of longitudinal axial members disposed about the circumference of the stents. According to this embodiment anywhere from one to ten or more axial

members may be used to provide a releasable restraint. The axial members may comprise cylindrical rods, flat or curved bars, or any other shape determined to be suitable.

In some situations, self expanding stents will tend to embed themselves in the inner wall of the outer sheath **114** over time. As illustrated in Figures **9D** and **10A**, a plurality of expansion limiting bands **121** may be provided to surround sections of the stents **12, 14** in order to prevent the stents from becoming embedded in the material of the sheath **114**. The bands **121** may be provided in any of a variety of numbers or positions depending upon the stent design. Figure **10A** illustrates the bands positioned at midpoints of each of the four proximal stent sections **127** and each of the five distal stent sections. In an alternative embodiment, the bands **121** are positioned over the ends of adjacent stent sections. The bands **121** may be made of stainless steel, or any other suitable metal or relatively non compliant polymer. Of course, many other structures may also be employed to prevent the self-expanding stents from embedding themselves in the plastic sheath. Such alternative structures may include a flexible coil, a braided tube, a solid-walled tube, or other restraint structures which will be apparent to those skilled in the art in view of the disclosure herein.

The inner surface of the outer sheath **114**, and/or the outer surface of the central core **112** may be further provided with a lubricious coating or lining such as Paralene, Teflon, silicone, polyimide-polytetrafluoroethylene composite materials or others known in the art and suitable depending upon the material of the outer sheath **114** and/or central core **112**.

Figure **10B** shows a distal portion of sheath **114** received in an annular recess 230 in the distal tip. As shown, at least the distal portion of the sheath **114** may comprise a two layer construction having an outer tube **213** and an inner tube or coating **212**. The exterior surface of the outer tube **213** is preferably adapted to slide easily within the vessels to be treated, while the inner surface is generally adapted to have a low coefficient of static friction with respect to the stents, thus allowing the sheath to slide smoothly over the stents. The outer tube **213** may, for example, be made of or coated with HDPE or PEBAX, and the inner tube **212** may, for example, be made of or coated with HDPE, PTFE, or FEP. In an embodiment in which the inner tube is made with a PTFE liner, however, the distal end **214** of the lubricious inner layer or tube **212** is preferably spaced proximally from the distal end **216** of the outer tube **213** by a distance within the range of from about 1 mm to about 3 mm. This helps prevent the stent from prematurely jumping distally out of the sheath during deployment due to the high lubricity of the PTFE surface.

Figure **10** illustrates one embodiment of a sheath retraction system. The system illustrated generally includes a sheath pull wire **222**, a pull wire slot **224**, a sheath retraction band **226**, and an outer sheath **114**. The sheath retraction band **226** may be a tubular element thermally or adhesively bonded or otherwise secured to a portion of the outer sheath **114**. In the illustrated embodiment, the retraction band **226** comprises a section of stainless steel tubing having an outside diameter of about 0.055 inches, a wall thickness of about 0.0015 inches and an axial length of 0.060 inches. However, other dimensions may be readily utilized while still accomplishing the intended function. The sheath retraction band **226** is positioned within the distal portion **117** of the outer sheath **114**, just distally of the diameter transition **119**. The retraction band **226** may be connected to the interior surface of the outer sheath **114** by heat fusing a pair of bands **225** to the inside surface of the outer sheath at each end of the retraction band (see Figure **9E**). Alternatively, the retraction band **226** can be attached to the outer sheath by using adhesives, epoxies, or by mechanical methods such as crimping and swaging or a combination of these. In this manner, the pull force which would be required to proximally dislodge the retraction band **226** from the outer sheath **114** is greatly in excess of the proximal traction which will be applied to the pull wire **222** in clinical use. The distal end of the pull wire **222** is preferably welded, soldered, bonded, or otherwise secured to the sheath retraction band **226**. The pull wire **222** may alternatively be bonded directly to the outer sheath.

The pull wire slot **224** is preferably of sufficient length to allow the sheath **114** to be fully retracted. Thus, the pull wire slot **224** is preferably at least as long as the distance from the distal end of the stent stop **218** to the distal end of the sheath **114** as shown in Figure **10A**. Slot lengths within the range of from about 1 cm to about 10 cm are presently contemplated for a two stent deployment system. With the sheath **114** in the distal position as shown, the pull wire slot **224** is preferably entirely covered by the proximal portion **115** of the sheath **114**. Alternatively, in an embodiment in which the proximal extension of sheath **114** extends the entire length of the catheter **100**, discussed above, it can be directly attached to the control **150**, in which case a pull wire **222** and slot **224** as shown might not be used.

In yet another embodiment illustrated for example in Figures **9B** and **9C**, a pull wire lumen **220** may terminate sufficiently proximally from the retraction band **226** that a slot as shown may not be used.

The pull wire **222** may comprise a variety of suitable profiles known to those skilled in the art, such as round, flat straight, or tapered. The diameter of a straight round pull wire **222** may be between about 0.008" and about 0.018" and in one embodiment is about 0.009". In another embodiment, the pull wire **222** has a multiple tapered profile with diameters of 0.015", 0.012", and 0.009" and a distal flat profile of 0.006" x 0.012". The pull wire **222** may be made from any of a variety of suitable materials known to those skilled in the art, such as stainless steel or nitinol, and may be braided or single strand and may be coated with a variety of suitable materials such as Teflon, Paralene, etc. The wire **222** has sufficient tensile strength to allow the sheath **114** to be retracted proximally relative to the core **112**. In some embodiments, the wire **222** may have sufficient column strength to allow the sheath **114** to be advanced distally relative to the core **112** and stents **12, 14**. For example, if the distal stent **12** has been partially deployed, and the clinician determines that the stent **12** should be re-positioned, the sheath **114** may be advanced distally relative to the stent **12** thereby re-contracting and capturing that stent on the core.

In general, the tensile strength or compressibility of the pull wire **222** may also be varied depending upon the desired mode of action of the outer sheath **114**. For example, as an alternative to the embodiment described above, the outer sheath **114** may be distally advanced by axially distally advancing the pull wire **222**, to release the stent **118**. In a hybrid embodiment, the outer sheath **114** is split into a proximal portion and a distal portion. A pull wire is connected to the proximal portion, to allow proximal retraction to release the proximal stent. A push wire is attached to the distal portion, to allow distal advance, thereby releasing the distal stent. These construction details of the catheter **100** and nature of the wire **222** may be varied to suit the needs of each of these embodiments, as will be apparent to those skilled in the art in view of the disclosure herein.

The stents **118** are carried on the central support core **112**, and are contracted radially thereon. By virtue of this contraction, the stents **118** have a cross section which is smaller than that of the conduits **32** and **34**, and they can be introduced into these as will be described below. The stents **118** are preferably disposed on a radially inwardly recessed distal portion **129** of the central core **112** having a smaller diameter than the adjacent portions of the core **112**. See Figure 12. This recess **129** is preferably defined distally by a distal abutment such as a shoulder **124** which may be in the form of a proximally facing surface on a distal tip **122**. Distal tip **122** has an outer diameter smaller than that of the

stents **118** when the stents are expanded, but greater than the diameter of the stents **118** when they are contracted. This abutment **124** consequently prevents distal advancement of the stents **118** from the core **112** when the stents **118** are contracted.

Proximal movement of the stents **118** relative to the core **112** is prevented when the stents are in the radially contracted configuration by a proximal abutment surface such as annular shoulder **125**. The distal abutment **124** and proximal abutment **125** may be in the form of annular end faces formed by the axial ends of annular recess **129** in the core **112**, for receiving the compressed stents **118**. See Figure **12**. In one embodiment, illustrated in Figure **10A**, the proximal abutment **125** is carried by a stent stop **218**. Stent stop **218** may be integral with or attached to the central core **112**, and has an outside diameter such that it is in sliding contact with the inside surface of outer sheath **114**. The compressed stent **14** will thus not fit between the stop **218** and the outer sheath **114**.

The deployment device **100** typically has a soft tapered tip **122** secured to the distal end of inner core **112**, and usually has a guidewire exit port **126** as is known in the art. The tapered distal tip **122** facilitates insertion and atraumatic navigation of the vasculature for positioning the stent system **118** in the area of the bifurcation to be treated. The distal tip **122** can be made from any of a variety of polymeric materials well known in the medical device arts, such as polyethylene, nylon, PTFE, and PEBAX. In the embodiment shown in Figure **10**, the distal tip **122** comprises an annular recess **230** sized and adapted to allow a distal portion of the outer sheath **114** to reside therein such that the transition between the tip and the outer sheath comprises a smooth exterior surface.

The distal tip **122** tapers in one embodiment from an outside diameter which is substantially the same as the outer diameter of the outer sheath **114** at the proximal end **128** of the tip **122** to an outside diameter at its distal end **130** of slightly larger than the outside diameter of a guidewire. The overall length of the distal tip **122** in one embodiment of the delivery catheter **100** is about 3 mm to about 12 mm, and in one embodiment the distal tip is about 8 mm long. The length and rate of taper of the distal tip **122** can be varied depending upon the desired trackability and flexibility characteristics. The tip **122** may taper in a linear, curved or any other manner known to be suitable.

With reference to Figures **11B** and **12**, a distal portion of the central core **112** preferably has a longitudinal axial lumen **132** permitting slideable engagement of the core **112** on a guidewire **170**. The guidewire lumen **132** preferably includes a proximal access

port **172** and a distal access port **126** through which the guidewire may extend. The proximal access port **172** may be located at a point along the length of the catheter **100**, as shown in Figures **11A** and **11B**, and discussed below (rapid exchange), or the proximal access port **172** may be located at the proximal end **102** of the catheter **100** (over the wire). In a rapid exchange embodiment, the proximal access port **172** is generally within about 25 cm of the distal access port **126**, and preferably is between about 20 cm and about 30 cm of the distal access port **126**. The guidewire lumen **132** may be non-concentric with the catheter centerline for a substantial portion of the length of the guidewire lumen **132**.

Figures **11A** and **11B** illustrate a transition between a proximal shaft tube **111** and a distal shaft tube **113** including a proximal guidewire access port **172** and a guidewire lumen **132**. The guidewire lumen **132** may extend through a coextrusion, or may be a separate section of tubing which may be bonded, bound by a shrink wrap tubing, or otherwise held relative to the proximal shaft tube **111**.

In the construction shown in cross-section in **Figure 11B**, a proximal shaft tube **111** having a pull wire lumen **220** is joined to a distal shaft tube **113** having a continuation of pull wire lumen **220** as well as a guidewire lumen **132**. In the illustrated embodiment, the proximal shaft tube **111** extends distally into the proximal end of connector tubing **230.** A mandrel is positioned within each lumen, and shrink tubing **236** is heated to bond the joint. An opening is subsequently formed in the shrink wrap to produce proximal access port **172** which provides access to the guidewire lumen **132**.

In one embodiment, the proximal shaft tube **111** comprises a stainless steel hypodermic needle tubing having an outside diameter of about 0.025" and a wall thickness of about 0.003". The distal end **123** of the hypotube is cut or ground into a tapered configuration. The axial length of the tapered zone may be varied widely, depending upon the desired flexibility characteristics of the catheter **100**. In general, the axial length of the taper is within the range of from about 1 cm to about 5 cm, and, in one embodiment, is about 2.5 cm. Tapering the distal end of the hypotube at the transition with the distal portion of the catheter provides a smooth transition of the flexibility characteristics along the length of the catheter, from a relatively less flexible proximal section to a relatively more flexible distal section as will be understood by those of skill in the art.

Referring to Figure **12**, a guidewire **170** is illustrated as positioned within the guidewire lumen **132**. As can be appreciated by those of skill in the art, the diameter of the

guidewire **170** is illustrated as slightly smaller (e.g., by about 0.001-0.003 inches) than the inside diameter of the guidewire lumen **132**. Avoiding a tight fit between the guidewire **170** and inside diameter of guidewire lumen **132** enhances the slideability of the catheter over the guidewire **170**. In ultra small diameter catheter designs, it may be desirable to coat the outside surface of the guidewire **170** and/or the inside walls of the guidewire lumen **132** with a lubricous coating to minimize friction as the catheter **100** is axially moved with respect to the guidewire **170**. A variety of coatings may be utilized, such as Paralene, Teflon, silicone, polyimide-polytetrafluoroethylene composite materials or others known in the art and suitable depending upon the material of the guidewire **170** or central core **112**.

As shown in Figure **12**, an inflation lumen **134** may also extend throughout the length of the catheter **100** to place a proximal inflation port in fluid communication with one or more inflatable balloons **116** carried by the distal end of the catheter.

The inflatable balloon **116,** if present, may be positioned beneath one or both stents, such as stent **14** as illustrated in Figure **12** or proximally or distally of the stent, depending upon the desired clinical protocol. In one embodiment, as illustrated in Figure **12**, the stent may be a self expandable stent which is initially released by proximal retraction by the outer sheath **114** as has been discussed. The balloon **16** is thereafter positioned in concentrically within the stent, such that it may be inflated without repositioning the catheter to enlarge and/or shape the stent. Post stent deployment dilatation may be desirable either to properly size and or shape the stent, or to compress material trapped behind the stent to increase the luminal diameter (e.g. angioplasty). In an alternate mode of practicing the invention, angioplasty is accomplished prior to deployment of the stent either by a balloon on the stent deployment catheter **100** or by a separate angioplasty balloon catheter (or rotational artherectomy, laser or other recanalization device). The stent deployment catheter **100** is thereafter positioned within the dilated lesion, and the stent is thereafter deployed. Thus, balloon dilatation can be accomplished using either the deployment catheter **100** or separate procedural catheter, and may be accomplished either prior to, simultaneously with, or following deployment of one or more stents at the treatment site.

As seen in Figure **9** and **9B**, the catheter also includes a handpiece **140** at the proximal end of the catheter **100**. The handpiece **140** is adapted to be engaged by the clinician to navigate and deploy the stent system **118** as will be described below. The

handpiece **140** preferably includes a control **150** adapted to control and indicate a degree of deployment of one or both stents. The control **150** is typically in mechanical communication with the sheath **114** such that proximal retraction of the control **150** results in proximal retraction of the sheath **114**. Those skilled in the art will recognize that distal motion, rotational movement of a rotatable wheel, or other motion of various controls **150** may alternatively be employed to axially move such as distally advance or proximally retract the sheath **114** to expose the stents.

The illustrated control **150** is preferably moveable from a first position to a second position for partial deployment of the first stent **12**, and a third position for complete deployment of the first stent **12**. A fourth and a fifth positions are also provided to accomplish partial and complete deployment of the second stent **14**. The control **150** may include indicia **160** adapted to indicate the amount of each stent **12** or **14** which has been exposed as the sheath **114** is retracted relative to the core **112**. The indicia **160** may include dents, notches, or other markings to visually indicate the deployment progress. The control **150** may also or alternatively provide audible and/or tactile feedback using any of a variety of notches or other temporary catches to cause the slider to "click" into positions corresponding to partial and full deployment of the stents **12, 14**. Alignable points of electrical contact may also be used. Those skilled in the art will recognize that many methods and structures are available for providing a control **150** as desired.

The catheter **100** may include a plurality of radiopaque markers **250** (seen best in **Figures 2, 10, and 10A)** impressed on or otherwise bonded to it, containing a radiopaque compound as will be recognized by those skilled in the art. Suitable markers can be produced from a variety of materials, including platinum, gold, barium compounds, and tungsten/rhenium alloy. Some of the markers **250A** may have an annular shape and may extend around the entire periphery of the sheath **114**. The annular markers **250A** may be situated, in the area of the distal end of the first stent **12**, the distal end of the second stent **14**, and in the area of the bridge **18** (FIG. 1) or space separating the stents **12, 14**. A fourth marker **252** may be situated at substantially the halfway point of the generatrix of the lower segment of the second stent **14** situated in the continuation of the bridge **18** and of the diametrically opposite generatrix. Figure **2** shows a marker **252** with a diamond shape and a small thickness provided along the outer sheath **114** at a desirable position for determining the rotational position of the catheter within the bifurcation. The markers **250**

and 252 may be impressed on the core **112**, on the sheath **114**, or directly on the stents **12, 14** such as on the bridge **18**, and not on the sheath **114**.

With reference to Figures **10** and **10A**, three markers **253** are shown disposed at a distal end of the second stent **14** and spaced at 120° relative to one another. Three markers **254** are also disposed at a proximal end of the first stent **12**, and spaced at 120° relative to one another. Each stent **12, 14** also includes a single marker **210** at its opposite end (e.g. the first stent **12** has a single marker **210** at its distal end, and the second stent **14** has a single marker **210** at its proximal end). Of course, other marker arrangements may be used as desired by the skilled artisan.

A central marker **252** makes it possible to visualize, with the aid of a suitable radiography apparatus, the position of a bridge **18** separating the two stents **12, 14**. Thus allowing a specialist to visualize the location of the second stent **14** so that it can be correctly positioned in relation to the widened zone **46**. The end markers **250A** allow a specialist to ensure that the stents **12, 14** are correctly positioned, respectively, in the main/principal conduit **32** and the secondary/branch conduit **34**.

A diamond-shaped marker **252** as shown in Figure **2** is, for its part, visible in a plan view or an edge view, depending on whether it is oriented perpendicular or parallel to the radius of the radiography apparatus. It thus makes it possible to identify the angular orientation of the stents **12, 14** in relation to the bifurcation **30**, so that the part of the second stent **14** having the greatest expansion can be placed in an appropriate manner in relation to the widened transition zone **46**.

Methods of positioning and deploying a pair of dissimilar stents in an area of a bifurcation will now be discussed with reference to **Figures 3-6** and **13-17**. Although portions of the following discussion refer to delivery of two dissimilar stent portions, those skilled in the art will recognize that a larger or smaller number of stents, and/or stents having similar expanded configurations may also be used while realizing certain aspects of the present invention.

A method of delivering a stent system as described above generally and illustrated in Figures **13-17** includes locating the bifurcation **30** to be treated, providing a suitable delivery catheter **100**, positioning the distal portion **107** of a delivery catheter with stents **12, 14** disposed thereon in the branch of the bifurcation to be treated, partially deploying the first stent **12** in a branch vessel **34**, observing and adjusting the position of the first stent

12 if necessary, then fully deploying the first stent 12. The second stent 14 is partially deployed, and preferably the position is again observed such as by infusing contrast media through the pull wire lumen 220 under fluoroscopic visualization. The position of the second stent 14 may be adjusted if necessary, and finally the second stent 14 is fully deployed. Methods of navigating catheters through blood vessels or other fluid conduits within the human body are well known to those skilled in the art, and will therefore not be discussed herein.

The delivery catheter 100 may be constructed according to any of the embodiments described above such that the stents 12, 14 may be selectively deployed by axially displacing the outer sheath 114 along the delivery catheter, thereby selectively exposing the stent system 10. This may be accomplished by holding the sheath 114 fixed relative to the bifurcation, and selectively distally advancing the central core 112. Thus, the present invention contemplates deploying one or more stents by distally advancing the central core (inner sheath) rather than proximally retracting the outer sheath as a mode of stent deployment. The stent system may alternatively be deployed by holding the central core fixed relative to the bifurcation and selectively proximally retracting the sheath 114. The catheter may also be adapted to allow the sheath to be advanced distally, thereby re-contracting the partially deployed stents on the central core 112 to allow repositioning or removal.

In order to visualize the position of a partially-deployed stent with a suitable radiographic apparatus, a contrast media may be introduced through the catheter to the region of the stent placement. Many suitable contrast media are known to those skilled in the art. The contrast media may be introduced at any stage of the deployment of the stent system 10. For example, a contrast media may be introduced after partially deploying the first stent 12, after fully deploying the first stent 12, after partially deploying the second stent 14, or after fully deploying the second stent 14.

The degree of deployment of the stent system 10 is preferably made apparent by the indicators on the handpiece 140 as described above. The handpiece 140 and outer sheath are preferably adapted such that a motion of a control on the handpiece 140 results in proximal motion of the outer sheath 114 relative to the distal tip 122 and the stents 12, 14. The handpiece 140 and sheath 114 may also be adapted such that the sheath may be advanced distally relative to the stents 12, 14, thus possibly re-contracting one of the stents

12, 14 on the core **112**. This may be accomplished by providing a pull wire **222** having a distal end **223** attached to a portion of the outer sheath **114**, and a proximal end adapted to be attached to the handpiece **140**. Alternatively, the handpiece **140** may be omitted, and the retraction wire **222** may be directly operated by the clinician.

In an alternative embodiment, indicated by Figures 4-6, the first and/or second stent **12, 14** may be deployed in a single motion, thus omitting the step of re-positioning the stent **12, 14** before fully deploying it. The sheath **114** is then progressively withdrawn, as is shown in **Figures 5** and **6**, in order to permit the complete expansion of the stents **12, 14**.

In a preferred embodiment, the second stent **14** is placed in close proximity to the first stent **12**. For example, the distal end **38** of the second stent **14** may be placed within a distance of about 4 mm of the proximal end **42** of the first stent **12**, more preferably this distance is less than about 2 mm, and most preferably the first and second stents **12, 14** are placed within 1 mm of one another. Those skilled in the art will recognize that the relative positioning of the first and second stents **12, 14** will at least partially depend on the presence or absence of a bridge **18** as discussed above. The axial flexibility of any bridge **18** will also affect the degree of mobility of one of the stents relative to the other. Thus, a stent system **10** will preferably be chosen to best suit the particular bifurcation to be treated.

As mentioned above, the stents **12, 14** may be self-expanding or balloon-expandable (e.g. made of a substantially non-elastic material). Thus the steps of partially deploying the first and/or the second stent may include introducing an inflation fluid into a balloon on which a stent is disposed, or alternatively the stent may be allowed to self-expand. In the case of a balloon-expandable second stent **14**, the balloon **116** (FIG. 12A) on which the second stent **14** is disposed may be specifically adapted to correspond to the particular shape of the second stent **14**. Specifically, such a balloon will preferably have a larger diameter at a distal end than at a proximal end.

After complete expansion of the stents **12, 14**, the distal end of the delivery catheter **100** including the core **112** and the guidewire **170** may be withdrawn from the conduits and the vasculature of the patient. Alternatively, additional stents may also be provided on a delivery catheter, which may also be positioned and deployed in one or both branches of the bifurcation. For example, after deploying the second stent **14** as shown in Figure **6** or **17**, the catheter **100** and guidewire **170** may be retracted and re-positioned in the second branch vessel such that a third stent may be positioned and deployed therein.

Referring to Figure 18, a second branch stent **13** may be deployed in the second branch, such that both branch vessels in the bifurcation are fully stented. The second branch stent **13** may be either a self expandable or balloon expandable stent such as those well known in the art and disclosed in part elsewhere herein. The second branch stent **13** may be deployed before or after the main stent **14** and/or first branch stent **12**. In one application of the invention, the main vessel stent **14** and first branch stent **12** are positioned as has been described herein. A stent deployment catheter (not illustrated) such as a balloon catheter or self expanding stent deployment catheter is transluminally advanced to the bifurcation, and advanced through the main vessel stent **14**. The second branch vessel stent **13** may then be aligned in the second branch vessel, such that it abuts end to end, is spaced apart from, or overlaps with the distal end of the main branch stent **14**. The second branch vessel stent **13** may then be deployed, and the deployment catheter removed.

As will be clear to those skilled in the art, the stent system **10** and stent delivery system **100** described herein is useful in treating a number of pathological conditions commonly found in vascular systems and other fluid conduit systems of human patients. Treatment with the apparatus can include re-establishing the appropriate diameter of a bifurcation in cases of arteriosclerosis or internal cell proliferation, or in rectifying a localized or nonlocalized dissection in the wall of the conduit, or in re-creating a bifurcation of normal diameter while eliminating the aneurysmal pouch in cases of aneurysm.

One or more of the stents deployed in accordance with the present invention may be coated with or otherwise carry a drug to be eluted over time at the bifurcation site. Any of a variety of therapeutically useful agents may be used, including but not limited to, for example, agents for inhibiting restenosis, inhibiting platelet aggregation, or encouraging endothelialization. Some of the suitable agents may include smooth muscle cell proliferation inhibitors such as rapamycin, angiopeptin, and monoclonal antibodies capable of blocking smooth muscle cell proliferation; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, acetyl salicylic acid, and mesalamine, lipoxygenase inhibitors; calcium entry blockers such as verapamil, diltiazem and nifedipine; antineoplastic/antiproliferative/anti-mitotic agents such as paclitaxel, 5-fluorouracil, methotrexate, doxorubicin, daunorubicin, cyclosporine, cisplatin, vinblastine, vincristine, colchicine, epothilones, endostatin, angiostatin,

Squalamine, and thymidine kinase inhibitors; L-arginine; antimicrobials such astriclosan, cephalosporins, aminoglycosides, and nitorfuirantoin; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; nitric oxide (NO) donors such as lisidomine, molsidomine, NO-protein adducts, NO-polysaccharide adducts, polymeric or oligomeric NO adducts or chemical complexes; anti-coagulants such as D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, enoxaparin, hirudin, Warafin sodium, Dicumarol, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet factors; interleukins, interferons, and free radical scavengers; vascular cell growth promoters such as growth factors, growth factor receptor antagonists, transcriptional activators, and translational promotors; vascular cell growth inhibitors such as growth factor inhibitors (e.g., PDGF inhibitor--Trapidil), growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin; Tyrosine kinase inhibitors, chymase inhibitors, e.g., Tranilast, ACE inhibitors, e.g., Enalapril, MMP inhibitors, (e.g., Ilomastat, Metastat), GP IIb/IIIa inhibitors (e.g., Intergrilin, abciximab), seratonin antagnonist, and 5-HT uptake inhibitors; cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogeneus vascoactive mechanisms. Polynucleotide sequences may also function as anti-restenosis agents, such as p15, p16, p18, p19, p21, p27, p53, p57, Rb, nFkB and E2F decoys, thymidine kinase ("TK") and combinations thereof and other agents useful for interfering with cell proliferation. The selection of an active agent can be made taking into account the desired clinical result and the nature of a particular patient's condition and contraindications. With or without the inclusion of a drug, any of the stents disclosed herein can be made from a bioabsorbable material.

The bifurcation **30** shown in Figure 3 has excrescences **35** which create a narrowing in cross section, which impedes the flow of the liquid circulating in the conduits **32** and **34**. In the case of a vascular bifurcation, these excrescences are due, for example, to arteriosclerosis or cellular growth. The stent system described herein permits treatment of this bifurcation by re-establishing the appropriate diameter of the conduits **32, 34** and of the widened transition zone **46**.

As shown in Figure 7, the stent system **10** can also be used to treat an aneurysm **242**. An aneurysm **242** is defined as a localized, pathological, blood-filled dilatation of a blood vessel caused by a disease or weakening of the vessel's wall. Thus it is desirable to provide a "substitute" vessel wall in an area of an aneurysm. For this purpose, the first or second stent **12, 14** may be at least partially covered by a film **240** which is substantially impermeable to the fluid circulating in the conduits **32, 34**. Many suitable films are known to those skilled in the art such as polyester, polytetrafluoroethylene (PTFE), high and medium density polyethylenes, etc. The film may be sewn onto the stents **12, 14**, or it may be folded around a stent such that as the stent is expanded within the vessel **32**, the film **240** is trapped and held between the stent and the vessel wall. The stent then guides the liquid through the bifurcation **30** and consequently prevents stressing of the wall forming the aneurysm **242**.

In some embodiments, each of the first (cylindrical) stent **12** and second (tapered) stent **14** can be provided on its own individual delivery catheter. With reference to Figures 19-22, embodiments of stent delivery systems for use in deploying a single stent for treatment of a pathology at a bifurcation are described below.

Figures 19 and 20 illustrate a system configured to deploy a single stent having a substantially straight or cylindrical shape when in its expanded condition, for example, the stent 12 could be substantially the same as the cylindrical stent 12 of the above embodiments. The system generally includes an elongate delivery catheter 100 substantially as described above and having a single stent 12 disposed on the distal end of the catheter. The stent 12 is surrounded by a retractable sheath 114 having a plurality of radial restraints such as retaining bands 121. In the illustrated embodiment, five retaining bands 121 are provided to retain the stent 12 in a compressed condition. Alternatively, other numbers of retention bands 121 may also be used. For example, one, two, three, four, or six or more retention bands 121 may be used as desired for a particular stent.

Figure 20 shows the system of Figure 19 with a proximal detail of the outer sheath 114. The delivery system for use with the straight stent 12 typically includes a stent stop 218 with an annular shoulder 125 which the proximal end of the stent 12 will abut as the sheath 114 is retracted. As shown in Figure 20, the stent stop 218 will abut the proximal markers 254 (in an embodiment having such markers) as the sheath is retracted by a

proximal force on the pull wire 222 which is attached to the sheath 114 at a retraction band 226.

Figures 21 and 22 illustrate a system configured to deploy a single stent having a substantially conical or otherwise tapered shape when in its expanded condition. For example, the conical stent 14 may be the same or similar to the main branch stent 14 described above. The system of Figure 21 generally includes an elongate delivery catheter 100 substantially as described above and having a single conical stent 14 disposed on the distal end of the catheter 100. The stent 14 is surrounded by a retractable sheath 114, which can include a radial retention structure such as a plurality of retaining bands 121. In the illustrated embodiment, four retaining bands 121 are provided to retain the stent 14 in a compressed condition and resist imprinting into the sheath 114. This number of retaining bands is particularly suited to the conical stent 14 according to one embodiment. Alternatively, other numbers of retention bands 121 may also be used. For example, one, two, three, five, or six or more retention bands 121 may be used as desired for a particular conical stent.

Figure 22 shows the system of Figure 21 with a proximal detail of the outer sheath 114. The delivery system for use with the conical stent 14 can include a stent stop 218 with an annular shoulder 125 disposed within the outer sheath configured to provide an edge against which the stent 14 may abut as the sheath is retracted. The stent stop 218 of the present embodiment illustrated in Figures 21 and 22, comprises a slot 211 in which the proximal marker 210 of the conical stent 14 may rest. By contrast, this slot 211 may be omitted in the embodiment illustrated in Figures 19 and 20 configured for use with a cylindrical stent, or if unnecessary in view of the particular conical stent design.

A delivery system adapted for use with a single stent will often be sized differently from the two-stent delivery system described above as will be apparent to those of skill in the art in view of the disclosure herein. For example, the axial length of the stent receiving recess 129 in a single stent delivery catheter will often be somewhat shorter than a dual-stent catheter. In general, the axial length of the stent receiving recess 129 in a single, tapered stent system for use in a bifurcation of the coronary artery will be within the range of from about 8 mm to about 18 mm, and often within the range of from about 10mm to about 13mm. The tapered stent for use in coronary applications is generally at least 10 mm in axial length, for example, 10mm, 11mm, 12mm, and 13mm can be used. For coronary

applications, the proximal expanded diameter is typically in the range of from about 3mm, to about 6mm, and often from about 3.5 mm to about 5.5mm, and in one embodiment the proximal expanded diameter is about 4.5 mm. The distal expanded diameter is typically in the range of from about 5mm, to about 8mm, and often from about 5.5 mm to about 7.5mm. In one embodiment of a tapered stent for use in coronary applications, the distal expanded diameter is about 6.5 mm. In one embodiment, the outer sheath 114 and the inner lumen of a single stent catheter can be about 11 mm shorter than the corresponding parts in a two-stent system.

A tapered stent for use in carotid or biliary applications generally has an axial length in the range of about 15mm up to about 20mm, and often between about 17mm and about 19mm. In one particular embodiment a tapered stent for use in carotid or biliary applications has an axial length of about 18mm. For carotid or biliary applications, the proximal expanded diameter is typically in the range of from about 8mm, to about 12mm, and often from about 9mm to about 11mm, and in one embodiment the proximal expanded diameter is about 10 mm. The distal expanded diameter is typically in the range of from about 11mm, to about 15mm, and often from about 12 mm to about 14 mm. In one embodiment of a tapered stent for use in coronary applications, the distal expanded diameter is about 13 mm. In general, the distal expanded diameter is generally at least about 40% of the axial length, and often the distal expanded diameter is more than 50% of the axial length.

The stent system described may be adapted as mentioned above to treat any of a number of bifurcations within a human patient. For example, bifurcations of both the left and right coronary arteries, the bifurcation of the circumflex artery, the carotid, femoral, iliac, popliteal, renal or other coronary bifurcations. Alternatively this apparatus may be used for nonvascular bifurcations, such as tracheal or biliary bifurcations, for example between the common bile and cystic ducts, or in the area of the bifurcation of the principal bile tract.

Although certain preferred embodiments and examples have been described herein, it will be understood by those skilled in the art that the present inventive subject matter extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the present inventive subject matter herein disclosed should not be limited by the

particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

WHAT IS CLAIMED IS:

1. A deployment system for treating a bifurcation of a main vessel and a first and second branch vessels, comprising:

an elongate, flexible body, having a proximal end and a distal end;

a first stent carried in a recess on the distal end of the body; and

a releasable restraint, for retaining the stent on the flexible body;

wherein the distal end of the stent is larger in diameter than the proximal end of the stent in an unconstrained expanded configuration.

2. A deployment system as in Claim 7, further comprising a guidewire lumen extending axially through at least a portion of the flexible body.

3. A deployment system as in Claim 8, wherein the guidewire lumen has a proximal access port and a distal access port, and the proximal access port is positioned along the flexible body, spaced distally apart from the proximal end.

4. A deployment system as in Claim 8, wherein the guidewire lumen has a proximal access port and a distal access port, and the proximal access port is positioned at the proximal end of the flexible body.

5. A deployment system as in Claim 7, wherein the releasable restraint comprises an axially movable control element extending along the length of the flexible body.

6. A deployment system as in Claim 7, wherein the releasable restraint comprises a tubular sheath.

7. A deployment system as in Claim 7, wherein the releasable restraint comprises a pull wire.

8. A deployment system as in Claim 7, wherein the releasable restraint comprises a dissolvable media.

9. A deployment system as in Claim 7, further comprising a second stent carried by the distal end of the body.

10. A deployment system as in Claim 15, wherein the first and second stents have different expanded geometries from each other.

11. A deployment system as in Claim 16, wherein the second stent has a substantially cylindrical unconstrained expanded configuration, having a proximal end, a distal end and a substantially constant radius throughout.

12. A deployment system as in Claim 7, wherein the expanded diameter of the first stent tapers radially outwardly in the distal direction.

13. A deployment system as in Claim 15, wherein the first and second stents are carried by the catheter such that release of the stents from the catheter causes the distal end of the first stent and the proximal end of the second stent, as implanted, to be separated by a distance of no more than about 4mm.

14. A deployment system as in Claim 19, wherein the distance is no more than about 2mm.

15. A stent deployment catheter, comprising:

an elongate, flexible tubular body, having a proximal end and a distal end;

a recess on the body, having an axial length within the range of from about 5 mm to about 20 mm;

a noncylindrical, self expandable stent carried by the recess ;

a handpiece on the proximal end; and

a control on the handpiece, for deploying the stent.

16. A stent deployment catheter as in Claim 23, further comprising a guidewire lumen, in an over the wire configuration.

17. A stent deployment catheter as in Claim 23, further comprising a guidewire lumen, in a rapid exchange configuration.

18. A system for treating a vascular bifurcation of a main vessel into first and second branch vessels, said system comprising:

a substantially cylindrical stent configured to be deployed in a first branch vessel which is distal to the bifurcation; and

a tapered stent configured to be deployed in the main vessel, proximal to the bifurcation;

wherein the tapered stent has a length within the range of from about 10 mm and about 20 mm, and tapers in the distal direction from a smaller proximal diameter to a larger distal diameter which faces the bifurcation.

19. The system for treating a vascular bifurcation as in Claim 21, further comprising a delivery catheter having a proximally retractable outer sheath configured to release at least one of the cylindrical stent and the tapered stent.

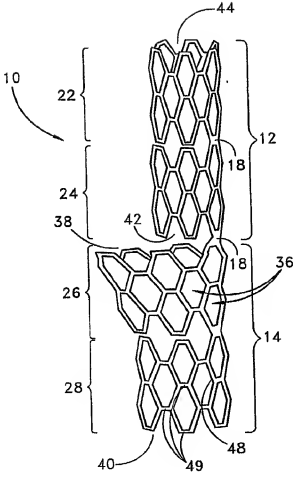
20. A system for treating a vascular bifurcation of a main vessel into a first and a second branch vessels, the system comprising:

a delivery catheter having a first stent thereon, the first stent having a proximal end and a distal end, a length of at least about 10 mm, and being self expandable to a configuration in which the proximal end has a smaller diameter than the distal end;

a releasable restraint configured to maintain at least one of the first and second stents in a compressed state until delivery of the stent;

wherein the distal end of the first stent expands to a diameter that is at least about 105% of the diameter of the proximal end of the first stent.

21. The system for treating a vascular bifurcation of a main vessel into a first and a second branch vessels as in Claim 1, wherein the distal end of the first stent expands to a diameter that is at least about 110% of the diameter of the proximal end of the first stent.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48

FIG. 1

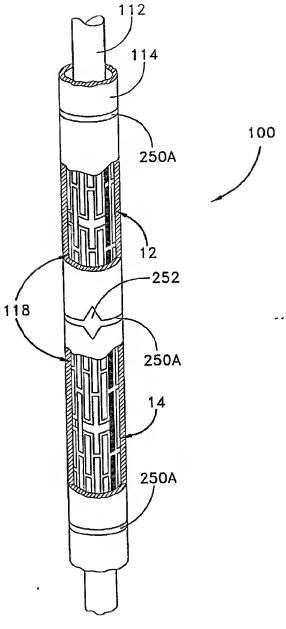
112
114
100
250A
12
252
118
250A
14
250A

FIG. 2

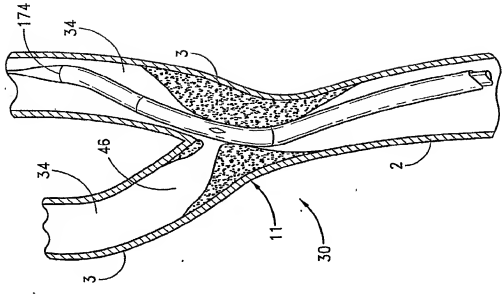

FIG. 4

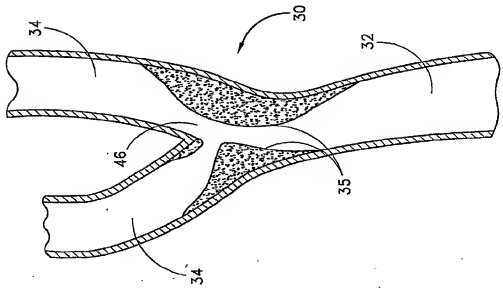

FIG. 3

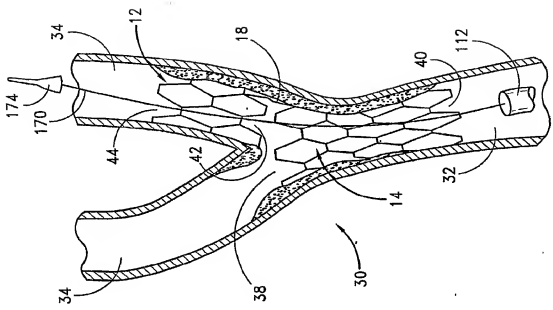
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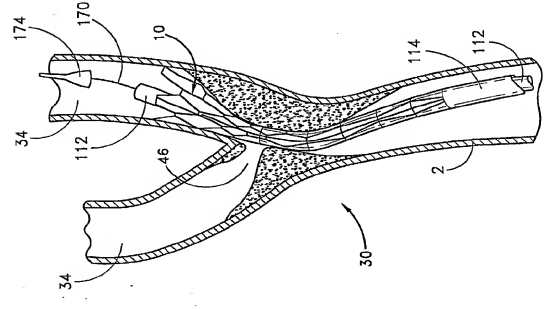
FIG. 6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170
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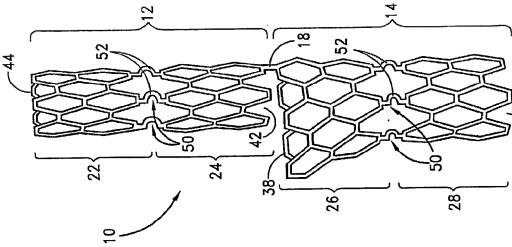
112
114
112
46
2
34
30

FIG. 5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22
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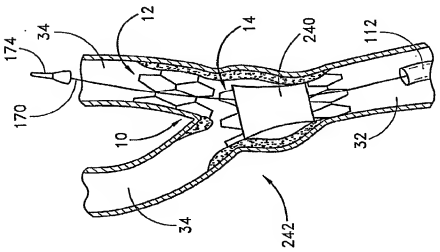
26
28
10

FIG. 8


174
34
12
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240
112
170
10
32
34
242

FIG. 7

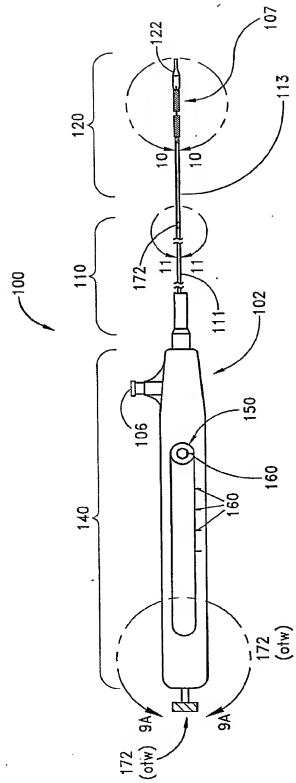

100
110
120
140
102
106
107
113
122
150
160
160
172
(otw)
172
(otw)
9A
9A
111
111
172
107
107

FIG. 9

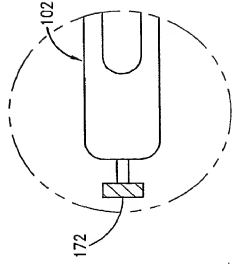

102
172

FIG. 9A

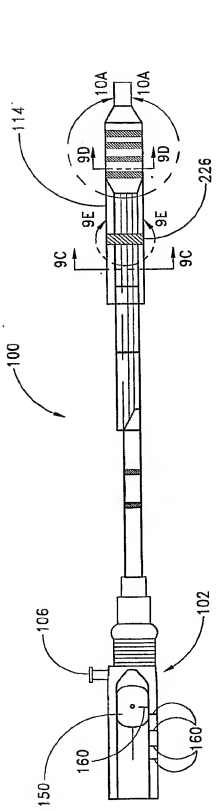


FIG. 9B

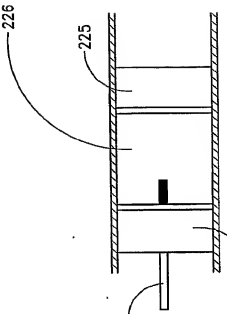


FIG. 9E

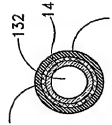


FIG. 9D

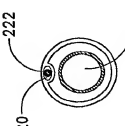


FIG. 9C

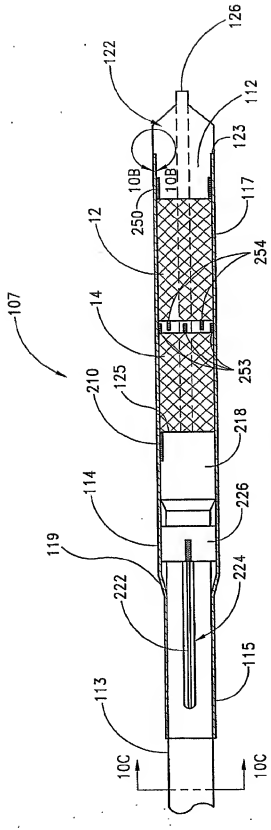


FIG. 10

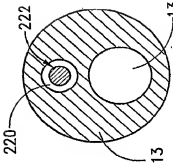


FIG. 10C

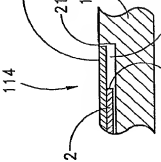


FIG. 10B

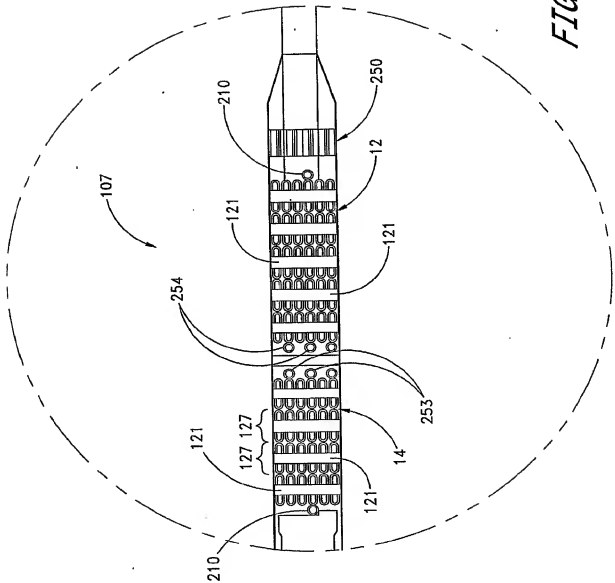


FIG. 10A

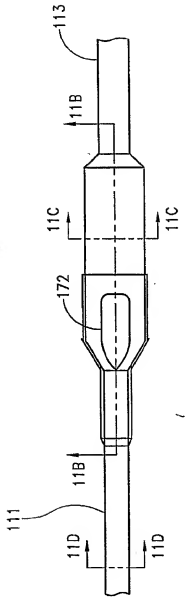


FIG. 11A

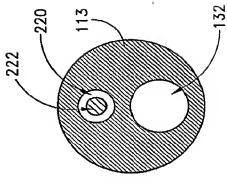


FIG. 11C

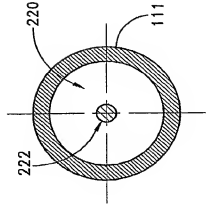


FIG. 11D

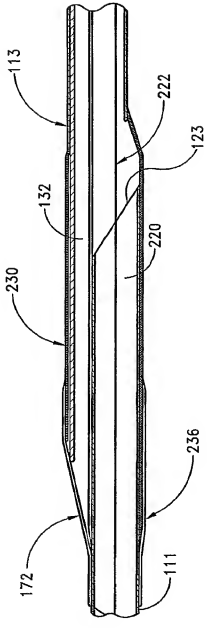
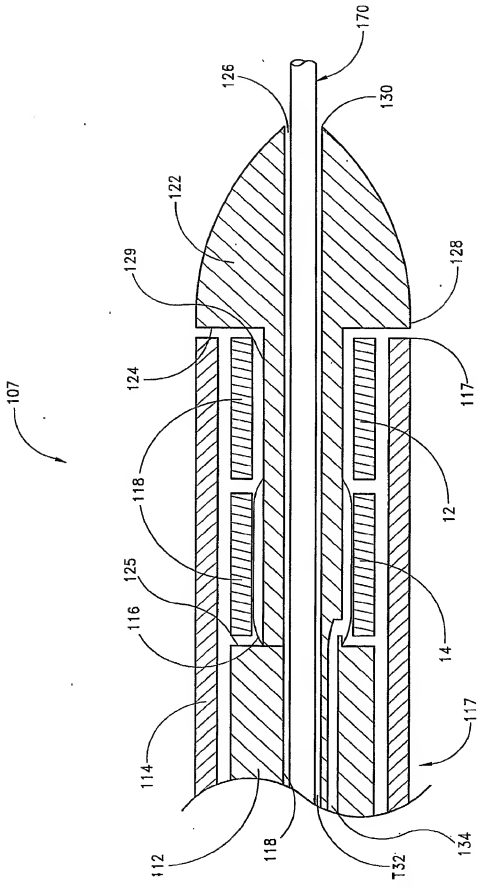


FIG. 11B


107
170
126
130
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129
128
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117
118
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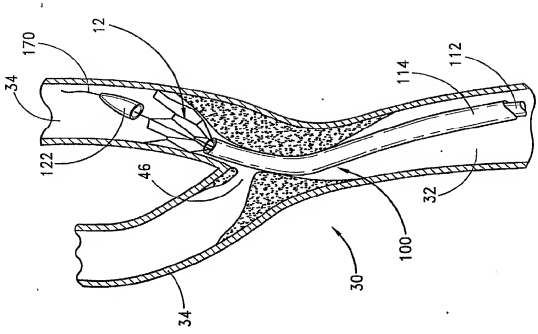
T32
134

FIG. 12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34
122
46
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112
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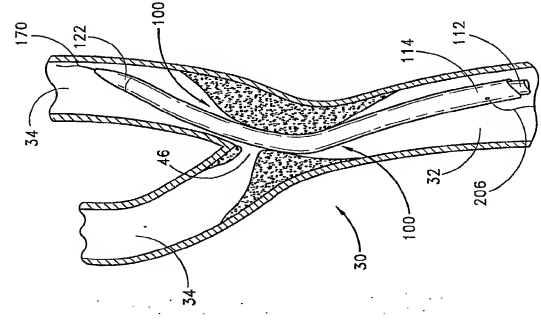
FIG. 14


170
122
100
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206
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FIG. 13

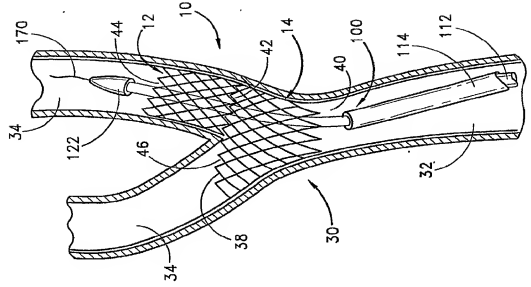


FIG. 17

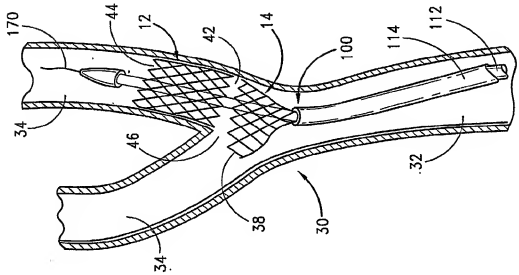


FIG. 16

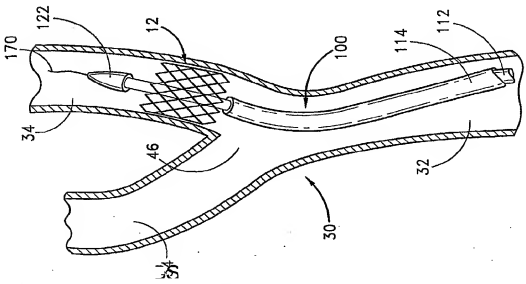


FIG. 15

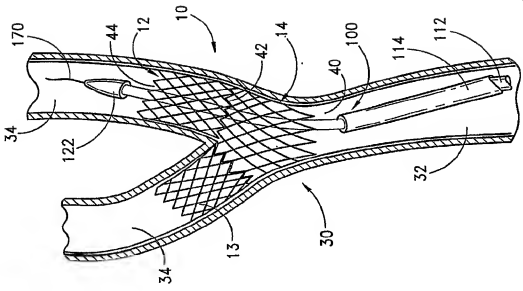
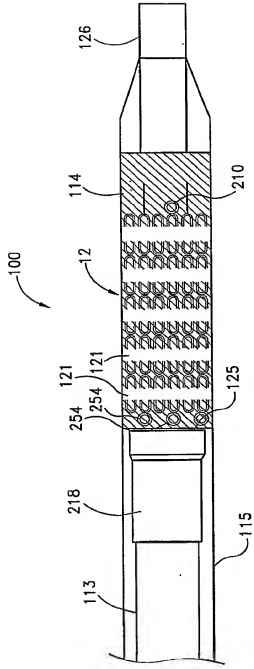


FIG. 18


126
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210
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254
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FIG. 19

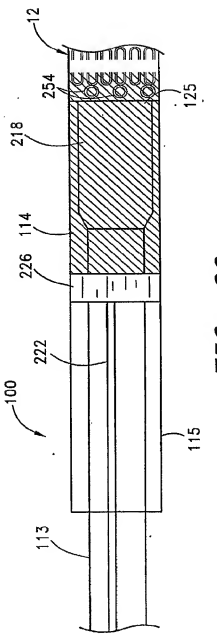
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FIG. 20

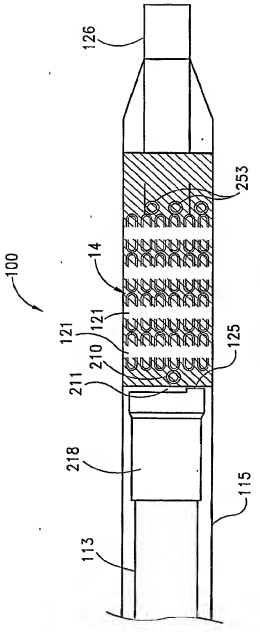
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FIG. 21

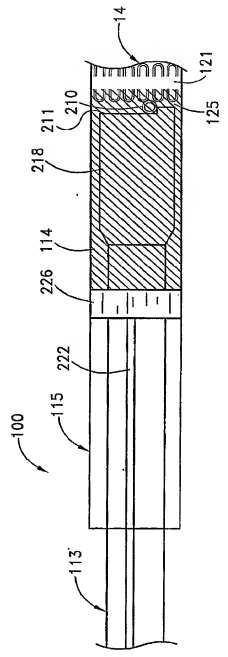
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FIG. 22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/35714

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/06
US CL. : 623/1.11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1.11, 604/264

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,676,696 A (MARCADE) 14 October 1997 (14.10.1997), See Figs. 1 and 9-10.	1,15, 13-15,18-21

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
20 February 2004 (20.02.2004)

Date of mailing of the international search report
19 APR 2004

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703)305-3230

Authorized officer
Thomas Barrett
Sharon N. Devine for

Telephone No. 703 308 8295

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/35714

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 2-6, 8-9 and 12 all depend from claim 7, which is dependent upon itself. Claims 11, 16 and 17 all depend on claim 23, however there is no claim 23.

2. ☐ Claim Nos.: 2-9,11,12,16 and 17
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.